

REMARKS:

The following remarks are submitted as a full and complete response to the Office Action issued on August 12, 2009. Claim 1 has been amended to recite that the formulation is a multi-layer tablet. Support for this claim amendment can be found throughout the specification, for example, at pages 9-11. Currently claims 1-16 are pending. Reconsideration of all outstanding rejections is respectfully requested in view of the following remarks.

Rejection under 35 U.S.C. §102(b)

The Patent Office has maintained its previous rejection of claims 1-16 under 35 U.S.C. §102(b) as anticipated by Shinoda et al. (U.S. Publ. Appln. No. 2003/0147948) ("Shinoda") for the reasons of record set forth at pages 3-4 of the previous Office Action dated December 31, 2008. The Patent Office alleges that Applicants' arguments presented in the previous Response appears to be made by considering Example 1 of Shinoda only, and "is unimpressive since the teachings of Shinoda et al. are clearly more extensive than only those teachings contained within Example 1." The Patent Office's arguments relied on the abstract, claims 1-5 and 9, Example 1, paragraphs [0019], [0031], [0052], [0055]-[0057] and [0074]. Applicants respectfully disagree.

As an initial matter, contrary to the Patent Office's understanding, Applicant's arguments in the previous response were made after fully considering the entire disclosure of Shinoda, not just Example 1. Nonetheless, in an effort to more clearly define the claimed formulation, Applicants have amended claim 1 to recite that the

claimed formulation is a multi-layer tablet. Thus, Applicants respectfully submit that Shinoda – considered in its entirety – still fails to teach or suggest all elements of claims 1-16 because it does not teach or suggest “a multi-layer tablet that comprises (a) a sustained-release core comprising an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions; (b) an enteric film coating layer coated on the sustained-release core; and (c) an active ingredient-containing film coating layer coated on the enteric film coating layer and comprising the active ingredient and a hydrophilic polymer for film coating.”

According to “BRIEF SUMMARY OF THE INVENTION” of Shinoda, Shinoda purports to provide “quick-disintegrating tablets” in the buccal cavity, which comprises sustained-release fine particles. [0009] of Shinoda. According to Shinoda, segregation of sustained-release fine particles and filler used in quick-disintegrating tablets in the buccal cavity causes various problems. *Id.* Shinoda further states that it successfully completed its invention upon discovering that such segregation can be prevented “by preparing a granulation product comprising sustained-release fine particles, several of which have aggregated together during this granulation process, using a granulation process whereby all or part of the surface of individual sustained-release fine particles is covered with filler.” *Id.*

Thus, Shinoda and the claimed invention are clearly distinguished in that a final product of Shinoda is a quick-disintegrating tablet, while the claimed invention provides a sustained release multi-layer tablet as a final product. More particularly, Shinoda discloses that “[t]his ‘tableting’ can be performed using, . . . , after adding the necessary additives, . . . to the above mentioned ‘composition,’” that is, a composition comprising

the product of granulation of sustained-release fine particles containing a drug and one more fillers. Thus, in Shinoda, all or part of the surface of the sustained-release fine particles via a granulation process is covered with filler in a quick-disintegrating tablet. However, nowhere does Shinoda teach or suggest that the sustained-fine particles are used in a sustained-release multi-layer tablet.

In contrast, in the claimed invention, the tablet itself is used for sustained release. To achieve this purpose, the claimed formulation is in the form of multi-layer tablet, which comprises (a) a sustained-release core comprising an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions; (b) an enteric film coating layer coated on the sustained-release core; and (c) an active ingredient-containing film coating layer coated on the enteric film coating layer and comprising the active ingredient and a hydrophilic polymer for film coating. Thus, as stated in the specification, the claimed sustained-release multi-layer tablet can efficiently prevent a burst drug release in the early phase of oral administration and continuously release a drug during a prolonged period of time.

Shinoda is silent as to providing a sustained-release multi-layer tablet, let alone a multi-layer tablet in the claimed structure. Instead, it relates to a quick-disintegrating tablet containing sustained release fine particles.

In view of the above, since Shinoda fails to teach or suggest each and every element of the claimed invention, it cannot anticipate claims 1-16. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

In light of the foregoing, Applicants submit that all outstanding rejections have been overcome, and the instant application is in condition for allowance. Thus, Applicants respectfully request early allowance of the instant application. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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By: _____


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